AUG 1 2 2005

K051703

510(k) Summary

Submitter's Information

Submitter's Name:	TaiDoc Technology Corporation
Contact person:	Shu-Mei Wu, Ph.D.
Address:	4F, No. 88, Sec. 1, Kwang-Fu Rd., San-Chung, Taipei County, Taiwan
Phone:	+886-2-66358080
Fax:	+886-2-66355959
E-mail:	shumei@taidoc.com.tw
Date Prepared:	June 21, 2005

1. Device

Trade Name: CLEVER TD-3018A™ Blood Pressure Monitor.
Common Name: Noninvasive Blood Pressure Measurement System
Classification Name: blood pressure monitor
Class II devices, 21 CFR 870.1130
Product Code: DXN

2. Predicate Device

Trade /Proprietary Name: APM Blood Pressure Monitor, BP108A
Common Name: Noninvasive Blood Pressure Measurement System
Classification Name: blood pressure monitor
Class II devices, 21 CFR 870.1130
Manufacturer: Asia Pacific Microsystems, Inc.
510 (k) Number: K040159

3. Device Description

The CLEVER TD-3018A™ Blood Pressure Monitor is a wrist blood pressure monitor and uses the oscillometric method to measure the blood pressure. The device includes setting button, function button, LCD display, start/stop button, recall

memory button, and wrist cuff. The symbols display on LCD include month, date, hour, minute, systolic rate, diastolic rate, pulse rate, pulse symbol, blood pressure unit, battery display, error symbol, memory record.
Both devices determine values of blood pressure by using oscillometric method. In this method, pulse waves are detected by using pressure sensors. Then the diastolic blood pressure, mean average pressure, and pulse pressure are derived. Furthermore, the systolic blood pressure and pulse rate are computed based on the information.

4. Intended Use

The intended use of CLEVER TD-3018A™ Blood Pressure Monitor is to measure human systolic, diastolic blood pressure and heart rate by using the oscillometric method. The measurement position of the device is the wrist of the subject.

5. Technology Characteristics Comparison

Both devices determine values of blood pressure by using oscillometric method. In this method, pulse waves are detected by using pressure sensors. Then the diastolic blood pressure, mean average pressure, and pulse pressure are derived. Furthermore, the systolic blood pressure and pulse rate are computed based on the information.

6. Non-clinical Performance

The results for non-clinical trials as presented in this document demonstrated the conformance to the SP10 standard that is also the reference standard for the predicate device. Therefore, the substantial equivalence between the devices is determined.

7. Clinical Performance

As the predicate device, the clinical test results of the TD-3018A showed the functions of the device met the criteria in the SP10 standard. Hence, it is reasonable to conclude the substantial equivalence between the devices.

8. Conclusions

The CLEVER TD-3018A Blood Pressure Monitor demonstrates satisfactory performance and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2 2005

Tai Doc Technology Corporation
c/o Mr. Shu-Mei Wu
Project Manager
4F No. 88, Sec1 Kwang-Fu Rd
Taipei County, Taiwan

Re: K051703
Trade Name: Clever T-D 3018A Blood Pressure Monitor
Regulation Number: 21 CFR 870. 1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: June 22, 2005
Received: June 24, 2005

Dear Mr.Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number: K051703

Device Name: *Clever TD-3018A* Blood Pressure Monitor

Indications For Use:

The *Clever TD-3018A* Blood Pressure Monitor provide intended to use non-invasive measure the systolic and diastolic blood pressure and pulse rate or an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.25"~7.75".

Prescription Use _____ AND/OR Over-The-Counter Use ___✓___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051703